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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|-----------------------|------------------|
| 10/695,762 | 10/30/2003 | Kenichi Matsunaga | 2003_1579A | 6906 |
| 513 | 7590 03/28/2006 | | EXAMINER | |
| WENDEROTH, LIND & PONACK, L.L.P. | | | SRIVASTAVA, KAILASH C | |
| 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | |
|---|--|---|--|--|
| Office Action Commence | 10/695,762 | MATSUNAGA, KENICHI | | |
| Office Action Summary | Examiner | Art Unit | | |
| | Dr. Kailash C. Srivastava | 1655 | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address - | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | l. ely filed the mailing date of this communication. 0 (35 U.S.C. § 133). | | |
| Status . | | | | |
| Responsive to communication(s) filed on <u>30 Occ</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowant closed in accordance with the practice under E | action is non-final. ace except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-14 are subject to restriction and/or explication Papers 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the original part of the specific and papers. | election requirement. .epted or b)□ objected to by the E | | | |
| Replacement drawing sheet(s) including the correcti | | | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449-or PTO/SB/08) | 4) Interview Summary Paper No(s)/Mail Da | | | |
| Paper No(s)/Mail Date | 6) Other: | , | | |

DETAILED ACTION

1. Your application is assigned to Dr. Kailash C. Srivastava in Art Unit 1655 at the United States Patent and Trademark Office (i.e., USPTO). To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

2. Claims 1-14 are pending.

Election/Restriction

- Restriction to one of the following inventions is required under 35 U.S.C. §121:
 - Group I Claims 1-2 and 4-5 drawn to a cancer preventing agent comprising an extract of different organelles of the fungus *Tricholoma matsutake*, classified under Class 424, Subclass 195.16 for example.
 - Group II Claim 3 drawn to a particular strain of *Tricholoma matsutake*, classified under Class 435, Subclass 34 for example.
 - Group III Claim 6 drawn to a composition to prevent colon cancer, classified under Class 424, Subclass 93.05 for example.
 - Group IV-Claim 7 drawn to a method to prevent cancer, classified under Class 514, Subclass 966 for example.
 - Group V-Claims 8-13 drawn to a food composition to prevent cancer, classified under Class
 426, Subclass 61 for example.
 - Group VI-Claims 14 drawn to a method to prevent cancer, classified under Class 424,
 Subclass 195.15 for example.

Inventions are Independent and Distinct

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-III and V are related to each other as sub-combinations disclosed as usable together in a single combination. The sub combinations are distinct from each other if they are

shown to be separately usable. In the instant case, an invention in each of Groups I-III and V has separate utility. For example invention in Group I is an alkaline or water extract of a fungal mycelium. The invention ascribed to Group V on the other hand is a food comprising a part of said fungus.

Inventions in Groups IV and VI are unrelated to each other because they are directed to different inventions that are not connected in design, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group IV are directed to a method to ameliorate cancer employing components that are different than those employed in the invention in Group VI and would therefore, may not be practiced together.

Inventions in Groups IV and VI are related to inventions in Groups I-III and V as a composition and a method to use said composition. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. In the instant case, the process of ameliorating a colon cancer encompassed in Group IV or VI invention is achievable with a variety of prescription medications known to those skilled in oncology. Likewise the composition in Groups I-III and V invention will be applicable as nutrients to an individual who may or may not be suffering from colon cancer.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I- IV in one single application. Furthermore, the criteria for patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

5. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. Currently, Claims 1, 7-8 and 14 are generic claims. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 6. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).
- The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.

Paterit Examiner Art Unit <u>1655</u> (571) 272-0923

March 19, 2006

RALPH GITOMER PRIMARY EXAMINER GROUP 1200

Recioner